

Remarks

Disposition of the claims

Prior to the instant amendment, Claims 1-16 were pending. Claims 1-2 were elected in response to the Examiner's restriction requirement mailed August 24, 2004, and Claims 3-16 were withdrawn from consideration pursuant to the same restriction requirement. By the foregoing amendment, Applicants have canceled Claims 1-2, and have added new Claims 17-28. Support for Claims 17-22 may be found throughout the Specification, and at least at Paragraph 0018, Example 8 at Paragraphs 0341-0350, and original Claim 1. Support for Claims 23-28 may also be found throughout the Specification, and at least at Paragraphs 0018-23 and Example 8 at Paragraphs 0341-0350. Accordingly, no new matter has been added. Claims 17-22 belong to the elected group. Claims 23-28 do not, but should be rejoined when the base vaccine claims are allowable.

Applicants note that language similar to that of Claims 17-28 was allowed and issued to Applicants in U.S. Patent No. 6,703,023.

Objection to the specification

The action requested that the cross-reference to related applications in the present specification be amended to refer to the patent number of the '245 application (the parent application of the present '264 application). Office action, 3. This request prompted the present amendment to the specification. Thus, the objection should be withdrawn.

Rejection Under § 112, ¶ 2

Claims 1-2 were rejected as indefinite for reciting the terms "homologous," "fragment," and "at least 80% identity." Office action, 4. Claims 1-2 were canceled, and thus the rejection is avoided.

Claims 17-28 avoid this rejection too. Claims 17-28 do not recite "homologous" or "fragment." Claim 18, e.g., recites the term "at least 90% sequence identity," a term which should allow one of ordinary skill in the art would to understand the bounds of the claim when read in light of the specification. Thus, as to these terms, the rejection is avoided.

Rejection Under § 112, ¶ 1 (enablement)

Claims 1-2 were rejected as non-enabled by the specification, because “[t]he current specification does not teach nor [enable] a vaccine to induce a protective response wherein upon introduction of the specific antigens or fragments thereof [into] a host a protective response can be inferred.” Office action, 5. Claims 1-2 were canceled, and thus the rejection is avoided.

Claims 17-28 avoid this rejection too. Claims 17-28 do not recite a “fragment.” Thus, as to this term, the rejection is avoided.

Furthermore, the rejection’s premise conflicts with the relevant disclosure of the present specification. Claims 17-28 recite “SEQ ID No 15,” which contains ORF’2 and ORF’1. These ORF’s, according to Example 8 of the present specification, were capable of producing protection: “Expression of PCV-B ORF’2 or PCV-B ORF’1 in swine resulted in a significantly enhanced level of protection as evaluated by weight evolution and body temperature evolution following challenge with PCV-B circovirus.” (Generally, paragraphs 341-50, pages 77-79; specifically, paragraph 349, page 79). Thus, it is submitted that a protective response can be inferred, and, therefore, an analogous rejection should not be made against claims 17-28.

Rejection Under § 112, ¶ 1 (written description)

Claims 1-2 were rejected as lacking a written description, because “[n]o other homologous sequences or fragments thereof were disclosed.” Office action, 6. Claims 1-2 were canceled, and thus the rejection is avoided.

Claims 17-28 avoid this rejection too. Claims 17-28 do not recite “homologous” or “fragment.” Thus, an analogous rejection should not be made against claims 17-28.

Rejections under § 102(e)

Claims 1-2 were rejected as anticipated under § 102(e) by the following four patents:

U.S. Pat. No. 6,368,601;

U.S. Pat. No. 6,660,272;

U.S. Pat. No. 6,391,314; and

U.S. Pat. No. 6,217,883.

Office action, 7-9. Claims 1-2 were canceled, and thus the rejection is avoided.

Furthermore, on one hand, claims 17-28 recite a *vaccine ... wherein said nucleic acid encodes an immunogenic protein that induces a protective response effective against infection by a piglet weight loss disease circovirus*. But, on the other hand, none of the cited patents describe such a *vaccine*, and thus these patents fail to anticipate claims 17-28.

Indeed, a patent may anticipate a claim only if it implicitly or explicitly describes each and every element in the claim. MPEP § 2131. Moreover, the patent must direct those skilled in the art to the presently claimed invention without any need for picking, choosing, and/or combining various disclosures in the patents not directly related to each other by the teachings of the cited reference. See *In re Arkley*, 172 U.S.P.Q. 524 (C.C.P.A. 1972); see also M.P.E.P. § 706.02(a) ("For anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly.") If, however, a single element is not described by the patent, then that patent fails to anticipate the claim. Such is the case here for each patent, which is addressed under a separate section

The '601 patent.

The rejection cited claim 26 of the '601 patent and states that "[t]he sequences disclosed meet the 'homologous'; 'fragment thereof'; and '80% identity' limitations." Office action, 8. Claims 17-28, however, do not recite "homologous" or "fragment." Thus, as to these terms, an analogous rejection should not be made against claims 17-28.

Moreover, the '601 patent fails to describe a *vaccine ... wherein said nucleic acid encodes an immunogenic protein that induces a protective response effective against infection by a piglet weight loss disease circovirus*. It is respectfully submitted that no passage from the '601 patent contains an enabling disclosure of the presently recited *vaccine*.

Furthermore, the claims of the '601 patent were not in the as-filed application that produced the '601 patent. For example, on November 30, 1999, well after the present

application's parent PCT (PCT/FR98/02634) application's filing date of December 4, 1998, Allen et al. filed an amendment canceling the original claims and replacing them with claims 38-69. In any case, the claims are no more enabling for these proposed embodiments than the other passages cited in the rejection. Accordingly, the claims do not anticipate the presently claimed invention.

In conclusion, none of the cited passages provides an enabling disclosure of all the elements of any rejected claim. Accordingly, the rejection should be withdrawn.

The '272 patent.

The rejection cited claims 1-2 of the '272 patent and reads as follows "The ['272] patent broadly disclosed an isolated circovirus II and various circovirus type II isolates, which would inherently have the now claimed sequence. Moreover, the SEQ ID NO: 1 as disclosed in the ['272] patent anticipates the broad limitations of the claimed invention." Office action, 9. Even if these statements were true, it is respectfully submitted that claims 17-28 would avoid this rejection, because the '272 patent fails to describe a *vaccine ...wherein said nucleic acid encodes an immunogenic protein that induces a protective response effective against infection by a piglet weight loss disease circovirus*. It is respectfully submitted that no passage from the '272 patent contains an enabling disclosure of the presently recited *vaccine*.

Also, the claims of the '272 patent were not in the as-filed application that produced the '272 patent. For example, on June 19, 2001, well after the present application's immediate parent (the '245 application's) application's filing date of February 28, 2000, Allen et al. canceled all as-filed claims and replaced them with claims 42-57. As a result, no claim from Allan et al. is evidence that the '272 patent described the presently claimed invention before the effective date of the presently rejected claims.

In conclusion, none of the cited passages provides an enabling disclosure of all the elements of any rejected claim. Accordingly, the rejection should be withdrawn.

The '314 patent.

The rejection cited claims 1-5 and 9 of the '314 patent and reads as follows "The product taught by the ['314 patent] is directed to nucleic acid of circovirus II and fragment thereof, which clearly incorporates the limitations of [the] now claimed invention." Office action, 9. Even if this statement were true, it is respectfully submitted that claims 17-28 would avoid this rejection, because the '314 patent fails to describe a *vaccine ... wherein said nucleic acid encodes an immunogenic protein that induces a protective response effective against infection by a piglet weight loss disease circovirus*. It is respectfully submitted that no passage from the '314 patent contains an enabling disclosure of the presently recited *vaccine*.

Also, the claims of the '314 patent were not in the as-filed application that produced the '314 patent. For example, on August 6, 2001, well after the present application's immediate parent (the '245 application's) application's filing date of February 28, 2000, Allen et al. deposited an amendment canceling claims and replacing them with claims 87-111. As a result, the claims from Allan et al. are not evidence that the '314 patent described the presently claimed invention before the effective date of the presently rejected claims.

In conclusion, none of the cited passages provides an enabling disclosure of all the elements of any rejected claim. Accordingly, the rejection should be withdrawn.

The '883 patent.

The rejection cited claims 1-2, 14, and 22-23 of the '883 patent and reads as follows: "The product taught by [the '883 patent] is directed to nucleic acid of circovirus II and fragment thereof, which clearly incorporates the limitations of [the] now claimed invention. In addition, the ['883 patent] disclosed the SEQ ID NO: 1 which anticipates the now claimed invention." Office action, 9. Even if these statements were true, it is respectfully submitted that claims 17-28 would avoid this rejection, because the '883 patent fails to describe a *vaccine ... wherein said nucleic acid encodes an immunogenic protein that induces a protective response effective against infection by a piglet weight loss disease circovirus*. It is

respectfully submitted that no passage from the '883 patent contains an enabling disclosure of the presently recited *vaccine*.

Also, the claims of the '883 patent were not in the as-filed application that produced the '883 patent. For example, on July 1, 1999, well after the present application's parent PCT (PCT/FR98/02634) application's filing date of December 4, 1998, Allen et al. filed the application that produced the '883 patent. It is respectfully submitted that each claim is entitled to a filing date no later than December 4, 1998. As a result, the '883 patent is not a proper § 102(e) reference against the present claims, because the claims from Allen et al. are not evidence that the '883 patent described the presently claimed invention before the effective date of the presently rejected claims.

In conclusion, none of the cited passages provides an enabling disclosure of all the elements of any rejected claim. Accordingly, the rejection should be withdrawn.

General Comments Concerning a New application filed since the last IDS

The IDS filed November 23, 2004, identified for the Examiner's convenience the related family members. Subsequent to the filing of this IDS, Applicants wish to update the Examiner about the filing of an additional family member. U.S. application no. 11/007,798 was filed on December 9, 2004, which application is pending and claims the benefit of U.S. Application no. 10/682,420, filed October 10, 2003 (Pending), which is a continuation of U.S. Application no. 10/637,011, filed August 08, 2003 (Pending), which is a continuation of U.S. Application no. 09/514,245, filed February 28, 2000, now Patent No. 6,703,023, which is a continuation-in-part of International Application no. PCT/FR98/02634, filed December 04, 1998. The mention of any application herein, including but not limited to the '798 application, is not a waiver of the application's secrecy.

Furthermore, on July 8, 2005, Applicants filed another application. As no application number has been assigned yet, no number is provided at this time.


Conclusion

Reconsideration and reexamination of the present application is respectfully requested. Please contact the undersigned if any matters may be resolved by a telephone conference.

Respectfully submitted,

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